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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Richard D. Gresham

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60 Middletown Avenue
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EXAMINER

MCEVOY, THOMAS M

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/522,914	Applicant(s) GRESHAM, RICHARD D.	
	Examiner Thomas Mcevoy	Art Unit 4123	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/28/2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on 1/28/2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/31/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claims 23-24 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 23-24 recite the limitation "a method according to claim 15". Claim 15 does not include any method. Examiner has interpreted this limitation to mean "a method according to claim 21" for the purposes of this examination.
2. Claim 22 is objected to because of the following informalities: The term "ab circular" in line 2 should read "a circular". Appropriate correction is required.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
2. Claims 7-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The recitation "normally held" in line 3 of claim 7 renders the claim indefinite in that it is not clear what constitutes being "normally held".

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-6, 21 and 25-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Graber et al. (US 5,370,647).

Regarding claim 1: A surgical instrument comprising: a body portion; a tool member supported on the distal end of the body portion [forceps (Figure 6 #102), not disclosed but obvious from the figure, have a body portion and a tool supported on the distal end]; and an elongated cover supported on the instrument in a first position wherein the tool member is uncovered, the cover being movable from the first position to a second position at least partially encompassing the tool member [cover (Figure 1 #52) and forceps are both moveable relative to each other within the instrument (column 6 lines 33-34 and 40-43) and therefore the cover can be moved to cover or uncover the tool member (forceps); this is also evident by comparing Figures 4-6 which show how the cover can be moved into and within the canula (#4) so that a first position where the tool member is uncovered is possible and a second position (Figure 6) where the tool member is covered is also possible].

Regarding claim 2: A surgical instrument according to claim 1, wherein the cover is liquid impermeable (column 8 lines 10-13).

Regarding claim 3: A surgical instrument according to claim 2, wherein a portion of the cover is fastened to the instrument (Figure 5 #52, column 5 lines 30-31).

Regarding claim 4: A surgical instrument according to claim 3 wherein the cover is tubular and has a proximal and a distal end and wherein the cover is open at the proximal and distal ends [the cover (Figure 6 #52) is clearly shown to be open at the distal end with the tool member extending through, therefore it is open at the opposing end as well].

Regarding claim 5: A surgical instrument according to claim 4, further including a cover deployment device operably associated with the cover, the cover deployment device being movable to move the cover from the first position to the second position [cover (Figure 1 #52) is attached to deployment device (Figure 1 #30, column 5 lines 30-31); this combination and the forceps are both moveable relative to each other within the instrument (column 6 lines 33-34 and 40-43) and therefore this combination can be moved to cover or uncover the tool member (forceps) which is also obvious from Figures 5-6].

Regarding claim 6: A surgical instrument according to claim 5, wherein the cover deployment device includes a sleeve slidably positioned about the body portion between a retracted and an advanced position, the sleeve being slidable from the retracted position to the advanced position to move the cover from the first position to the second position [the sleeve (Figure 1 #30) is slidable relative to the body portion as described above for claims 1 and 5 (column 6 lines 33-34 and 40-43) and obvious from Figures 5-6].

Regarding claim 21: A method of performing a surgical procedure comprising the following steps: providing a surgical instrument including a body portion, a tool member and a cover [forceps (Figure 6 #102), not disclosed but obvious from the figure, have a body portion and a tool supported on the distal end], the cover being supported on the instrument and movable from a first position wherein the tool assembly is uncovered to a second position wherein the tool member is at least partially covered [cover (Figure 1 #52) and forceps are both moveable relative to each other within the instrument (column 6 lines 33-34 and 40-43) and therefore the cover can be moved to cover or uncover the tool member (forceps) which is also obvious from Figures 5-6]; positioning the surgical instrument adjacent a surgical site and performing a surgical operation on desired tissue (column 6 lines 35-42); moving the cover from the first position to the second position [not specifically disclosed in the text but it is obvious from Figure 6 where the deployment device (#30) has additional length which can be further inserted into the cannula (#4) which can move the cover (#52) over the tool member (forceps, no

Art Unit: 3726

reference number given) which is equivalent to moving the cover from the first position to the second position as claimed]; and subsequently removing the surgical instrument from the surgical site (column 6 lines 48-52).

Regarding claims 25 and 26: A method according to claim 21, wherein the surgical instrument includes a closure device, and further including the step of actuating the closure device to close the cover at a location distally of the tool member; and a method according to claim 25, wherein the closure device is a drawstring (Figure 24, column 10 lines 26-28).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 7-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Graber et al. (US 5,370,647) in view of Orban (US 2004/0242960).

Regarding claim 7: Graber et al. disclose a surgical instrument according to claim 6 (as described above) wherein the sleeve includes first and second half-sections [the struts or wires (Figure 2 #39, Figure 10 #511) are symmetrically arranged about the sleeve (Figure 2 #30, Figure 10 #300) and therefore can be divided into several sections including half sections]. Graber et al. do not disclose the first and second half-sections being normally held in abutment with one another by at least one expandable member, the expandable member being expandable to permit the first and second half-sections to move outwardly with respect to each other. Attention is drawn to Orban who discloses a very similar surgical instrument to Graber et al. where the struts or wires (Figure 1B #28) are connected by an expandable hoop (Figure 1B #35), which can permit expansion or contraction of the struts or wires which comprise the half-sections (paragraph 0027). Therefore it would have been obvious to one of ordinary skill in the art, having the teachings of Graber et al. and Orban before him or her to have combined the expandable hoop of Orban with the invention of Graber et al. in order to facilitate contraction of the cover before or after deployment.

Regarding claim 8: Graber et al. do not disclose a surgical instrument according to claim 7 wherein the expandable member is a resilient O-ring. Orban discloses that the expandable hoop can have shape memory (paragraph 0029) thereby making it a

resilient O-ring according to the broadest definition of the term. Therefore it would have been obvious to one of ordinary skill in the art, having the teachings of Graber et al. and Orban before him or her to have combined the expandable hoop with shape memory of Orban with the invention of Graber et al. in order to facilitate contraction of the cover before or after deployment.

Regarding claim 9: A surgical instrument according to claim 7, wherein the sleeve includes a proximally located annular ring dimensioned to facilitate movement of the sleeve between the retracted and advanced positions [the handle (Figure 1 #20) is tubular or ring shaped and dimensioned to facilitate movement of the sleeve (column 4, lines 41-44)].

Regarding claim 10: Graber et al. disclose do not disclose a surgical instrument according to claim 9 wherein the first sleeve half-section includes at least one projection and the second sleeve half-section includes at least one slot, the at least one projection being slidable into the at least one slot to maintain alignment between the first and second half-sections when the half-sections move outwardly with respect to each other. Orban discloses the expandable hoop as described for claims 7 and 8 which also is composed of two telescoping and reciprocating sections (paragraph 0027). As can be seen from Figure 1B, the hoop (#35) joins the struts (#28) and therefore maintains their rotational alignment. Since the hoop is composed of two telescoping sections, one must contain a projection which is slidable into the hole or slot of the other. Therefore, it

would have been obvious to one of ordinary skill in the art, having the teachings of Graber et al. and Orban before him or her to have combined the expandable hoop of Orban with the invention of Graber et al., where one section of the hoop is attached to one group of struts (sleeve half-section) and the other section of the hoop is attached to the other group of struts (sleeve half-section), in order to maintain rotational alignment of the struts as they expand outward during deployment.

Regarding claim 11: A surgical instrument according to claim 10, wherein the cover includes a proximal end and a distal end and defines a lumen, the distal end of the cover being fastened to the surgical instrument on or adjacent the tool member such that the cover lumen is positioned about the body portion and the cover deployment device [the tool member can be inserted through the deployment device which includes the cover (Figure 1 #30 and #52, column 4 lines 59-62) therefore the cover lumen would be fastened to the surgical instrument adjacent to the tool member depending upon the relative position of the tool member and the deployment device], wherein movement of the cover deployment device from the retracted position to the advanced position inverts the cover [although not specifically disclosed in the text but evident from the drawings, the cover can be outwardly flared during deployment from a position where it is tucked within the deployment device, therefore inverting it (Figure 24)].

Regarding claim 12: A surgical instrument according to claim 11, wherein the cover deployment device includes a distal engagement member, a proximal guide portion and

a central body portion interconnecting the engagement member and the guide portion [the handle (Figure 1 #20) guides the deployment device (column 4, lines 41-44) and is connected by a central body portion (Figure 1 #30) to the distal end of the deployment device - composed of wires or struts (Figure 2 #39 or Figure 10 #511), the distal end capable of expanding to surround or engage the tool member (column 6 lines 54-56)], the cover deployment device being slidably supported on the body portion to enable the cover deployment device to be moved to move the cover to the second position (explained above for claims 5-6).

Regarding claim 13: A surgical instrument according to claim 12, wherein the cover includes a tubular member defining a lumen [it is evident from Figure 1 that cover (#52) is a tubular member defining a lumen], one end of the cover being fastened to the instrument, the other end of the cover being movable over the tool member to at least partially encompass the tool assembly (explained above for claims 5-6).

Regarding claim 14: A surgical instrument according to claim 13, further including a closure device for closing the other end of the cover after it has moved over the tool member (explained above for claims 5-6 and 25-26).

Regarding claim 15: A surgical instrument according to claim 14, wherein the closure device includes an elastic band supported by the cover (the closure device can be a

drawstring as explained for claims 25-26 above, where it is known to one of ordinary skill that drawstrings may be elastic).

Regarding claim 16: A surgical instrument according to claim 14, wherein the closure device includes a drawstring (explained above for claims 25-26).

Regarding claim 17: Graber et al. do not disclose a surgical instrument according to claim 16 wherein the distal end of the cover is removably fastened to the surgical instrument. Orban discloses that the cover may be removably fastened to the surgical instrument to facilitate removal of the excised tissue through the instrument (paragraph 0030). Therefore, it would have been obvious to one of ordinary skill in the art, having the teachings of Graber et al. and Orban before him or her to have combined the removable cover of Orban with the invention of Graber et al. in order to facilitate removal of the excised tissue through instrument.

8. Claims 18-20 and 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Graber et al. (US 5,370,647) in view of Orban (US 2004/0242960) and in further view of Graber et al. (same reference).

Regarding claims 18-20 and 22-25: Graber et al. in view of Orban disclose the invention as described above but does not disclose a surgical instrument according to claim 17 or a method according to claim 21 wherein the surgical instrument is a circular stapler, a

linear stapler, or an ultrasonic dissector. Attention is directed back to Graber et al. who disclose that the scope of their invention encompasses laparoscopic surgery for extracting tissue and/or implanting prosthesis (column 2, lines 16-19). Therefore, it would have been obvious to one of ordinary skill in the art, having the teachings of Graber et al. and Orban before him or her to have used the invention, as described above, in combination with a circular stapler, a linear stapler, or an ultrasonic dissector because these instruments are useful in laparoscopic surgery for extracting tissue and/or implanting prosthesis.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas Mcevoy whose telephone number is 571-270-5034. The examiner can normally be reached on M-F, 7:30-5:00 (alternate Fridays).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joe Del Sole can be reached on 571-272-1130. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

Art Unit: 3726

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TM

/Essama Omgba/
Primary Examiner, Art Unit 3726